



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/447,820	05/23/95	EKINS	R

18M1/1210
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EXAMINER	
WOODWARD, M	
ART UNIT	PAPER NUMBER
1815	11

DATE MAILED:

12/10/97

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

a) ☒ is extended to run _____ or continues to run 3 Mo. from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 11/28/97 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

a. ☒ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

b. ☐ They raise new issues that would require further consideration and/or search. (See Note).

c. ☒ They raise the issue of new matter. (See Note).

d. ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: THE AMENDMENT TO THE SPECIFICATION
CONSTITUTES NEW MATTER.

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

Claims allowed: _____

Claims objected to: _____

Claims rejected: 1-8

However;

☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because 565
ATTACHED

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

The Berger Declaration under 37 CFR 1.132 filed November 28, 1997 is insufficient to overcome the rejection of the claims based upon Ekins and Chen et al. as set forth in the last Office action because:

At paragraph 3 Berger states:

5 We were already aware of his work at that time, but were quite skeptical as to whether it would be applicable to the development of sensitive assays, since the notion of reducing the amount of binding agent in relation to the analyte to detect the analyte runs counter to the accepted concept that large
10 amounts of binding agent are required to achieve high levels of analyte binding to gain maximum sensitivity.

It is unclear, how, when confronted with a set of binding equations which clearly demonstrate the correctness of Ekin's hypothesis could fail to recognize that the prevalent concept in the art needed adjustment. Moreover, given the Ekins results it is unclear how one of ordinary skill in the art could cling to the concept. Having
15 demonstrated his concept Ekins made it available to those of ordinary skill in the art. Given the equations of Ekins one would proceed to optimize the assay as one saw fit.

At paragraph 5 Berger speaks to what artisans were doing but not what they would have done following a reading of Ekins. That the art continued along a
20 particular pathway despite the teachings of Ekins does not render his teachings unobvious nor does it preclude extending them.

Berger repeatedly states that he believes, but he fails to demonstrate how given the Ekins results and equations such a belief has a logical basis.

It is clear either from the teachings of Ekins or from first principles that one
25 should monitor the amount of binding agent present in the assay so as to most accurately determine the amount of analyte present in a sample. The issue is how

one is to make such a measurement.

Clearly, labelling the capture reagent provides a means for determining the amount of capture reagent present.

In paragraph 7 while attempting to dismiss Chen et al. Berger states:

5 In practice, a fluorescent tag on the antibody and a fluorescent tag on the back-titration agent are detected quantitatively while they are bound to each other, using the same fluorimeter, and the quantity of ligand present in an unknown sample is determined as a function of the ratio of the quantitative measurements of the two stages.

10 This statement of what was known should be compared with the instant specification at page 11, lines 7-23.

Later in paragraph 7 Berger attempts to repudiate the combination of Chen et al. with Ekins by asserting that affixation of the correct amount of binding agent to a test surface during manufacture is unimportant in the instant assay because the
15 instant assay is independent of the amount of binding agent is illogical and contradictory. In order to employ the Ekins assay one must know the amount of binding agent present.

Finally, it is unclear that Berger is an objective witness given his statements in paragraph 4 regarding the financial investments made by Boehringer Mannheim.

20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to MP Woodward whose telephone number is (703) 308-3890. The examiner can normally be reached on Monday-Friday from 7:30 AM to 5:00 PM. In the event that the examiner does not personally answer the telephone his voice mail will provide the necessary instructions.

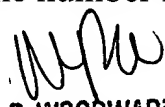
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311.

Currently a plurality of official and unofficial fax lines are available. However, changes in fax location occur with frequency. Please contact the
5 examiner to obtain the currently operative fax numbers.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


MICHAEL P. WOODWARD
PRIMARY EXAMINER
GROUP 1800

December 9, 1997